

REMARKS

Claims 52-69 are currently pending in this Application, with claim 69 being added with this Response. Claims 52, 54, and 55 have been amended with this Response.

Objections to the claims

Claims 52 and 54 are objected to for informalities. In response, Applicant respectfully amends these claims.

Claim Rejections Under 35 U.S.C. §112 second paragraph

Claims 52-67 are rejected for being indefinite. In Response, Applicant respectfully amends claim 52.

Claim Rejections Under 35 U.S.C. §112 first paragraph

Claims 52-68 are rejected for allegedly not complying with the written description requirement. Specifically, the Examiner alleges the “distinguishing criterion” recited in claims 52 and 68 are not disclosed in the Specification. Applicant respectfully traverses this allegation.

Applicant respectfully refers the Examiner to page 13, lines 14-18, which states that in connection with the set up procedure, that the maximal level of activity as well as normally occurring levels of activity are registered by the apparatus and are utilized for establishing criteria for releasing the feedback signal. This passage discloses a direct example of the requirement of claim 52 and claim 68 that the apparatus processes the first reference signals (indicative of other muscle activity – in this case the normally occurring muscle activity) and the second reference signals (indicative of a particular muscle activity (in this case the expected maximal level of muscle activity), and identifies from these two kinds of reference signal at least one distinguishing criterion which differentiates them. This is then used as the basis for triggering the feedback signal. Page 7, line 18 provides similar teaching.

The above is also exemplified at page 29, lines 6-13, wherein during a setup phase of use “all the personal parameters related to bruxism are registered and stored in a personal table.” An example of a suitable criterion given there is a match in the detected signals to the 1st harmonic frequency to that characterising bruxism which is registered in the setup mode.

Applicant respectfully submits that these general and specific passages describe to the reader the subject matter in question so as to convey to the reader that the subject matter was possessed by the inventor at the time of filing. As such, the 112, first paragraph rejection is respectfully overcome.

Claim Rejections Under 35 U.S.C. §102(b)

Claims 52-59, 62, 65, and 67-68 are rejected under 35 U.S.C. §102(b) as being anticipated by United States Patent No. 6,669,477 to Ober (hereinafter “Ober”). Applicant respectfully traverses the rejections.

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. V. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Applicant’s claim 52 recites, *inter alia*,

“a set-up mode and in a use mode, said set-up mode being distinct from said use mode,

and wherein, in said set-up mode, said apparatus is user controllable to receive as a first reference input signals from said means for providing signals which are indicative of

said other muscle activity and to separately receive second reference input signals from said means for providing signals which are indicative of said particular muscle activity, and wherein said apparatus is configured in said set-up mode to process said first reference signals and said second reference signals to identify therefrom at least one distinguishing criterion which differentiates said first reference input signals from said second reference input signals,” and

claim 68 similarly recites *inter alia*;

“a set-up mode and in a use mode, said set-up mode being distinct from said use mode,

and wherein, in said set-up mode, said apparatus is user controlled to receive as a first reference input signals from said means for providing signals which are indicative of a said other muscle activity and to separately receive as a second reference input signals from said means for providing signals which are indicative of said particular muscle activity,

and wherein said apparatus is configured in said set-up mode to process said first reference signals and said second reference signals to identify therefrom at least one distinguishing criterion which differentiates said first reference input signals from said second reference input signals.”

Ober does not teach a set-up mode that is distinct from a use mode at all, and certainly does not teach a set-up mode involving receipt of two kinds of reference signal or a process that identifies at least one distinguishing characteristic therefrom.

Referring first to a set-up mode in general, Applicant respectfully asserts that the Examiner goes beyond any reasonable interpretation of Ober when stating at page 8 of the Office action that a set-up mode is inherent (i.e. necessary) because one would not adjust the threshold during use when the patient is sleeping, since bruxism is not a predictable event during sleep. Instead of identifying an “inherent” function of Ober, the Examiner is

more accurately assigning a mode to Ober that is far from inherent/essential to the Ober device or procedure. In fact, there is no barrier to a clinician monitoring the sleep of a patient for a period, and adjusting the threshold when observing bruxism in the patient. That would actually be perfectly sensible, since only during bruxism would one have certainty that the actual signals were above where the threshold should be set. Ober contains no teaching that bruxism signals can be simulated.

Even if the threshold is adjusted prior to actual use (which, again, would not be inherent to the teaching of Ober), it would certainly not be inherent that such an adjustment would be in the context of any receipt of two kinds of signals in a set-up mode as required by the recitation of “said apparatus is user controlled to receive as a first reference input signals from said means for providing signals which are indicative of a said other muscle activity and to separately receive as a second reference input signals from said means for providing signals which are indicative of said particular muscle activity,” in the claims. In fact, one could simply use trial and error, starting with a level which works for other users and seeing how the patient’s sleep is affected, turning down the level if the patient reports that sleep is too much disturbed and turning it up if bruxism does not seem to be halted. That would not be what the claims call for. It would not involve receiving two kinds of reference signal during the set-up.

Even if one were to modify the above by having the device active whilst adjusting the threshold, perhaps setting it somewhat above the signal level produced by a resting patient, that would not meet the claim in that only one class of reference signal would be involved. Accordingly, Applicants claims would be neither inherently taught by (102) or obvious over (if 103 were to be applied) Ober.

Furthermore, even if, *pro arguendo*, Ober taught receipt of two kinds of signals in a set-up mode, Ober would still not teach (inherently or otherwise) the identification element recited in Applicant’s claims, “wherein said apparatus is configured in said set-up mode to process said first reference signals and said second reference signals to identify therefrom

at least one distinguishing criterion which differentiates said first reference input signals from said second reference input signals.” Applicant respectfully points out that threshold adjustment is taught to occur in Ober via a manual turning of knob 32. Contrary to this manual turning, the above quoted element of Applicant’s claims requires that the device be capable of determining the relevant distinguishing criterion. Whilst the Examiner contends that Ober discloses the processing of the signals that are above and below threshold, because ‘otherwise the device would not be capable of determining the feedback threshold’, we respectfully point out that this is not what the device of Ober does. The device of Ober does not determine/process and identify the feedback threshold. The threshold is merely set by an operator turning the knob 32 as they judge fit. If that judgment takes in any note of the signals coming from the sensing electrodes at all (and that is not described) it is a judgment of the operator and not of the device.

Accordingly, nothing in the device described by Ober identifies from the first and second reference signals a distinguishing criterion on the basis of which the two sorts of reference signals can be differentiated. If that criterion, per the Examiner, is considered to be whether the signals are above or below a threshold intensity, this is not something which is worked out by the device of Ober in a set-up procedure.

In fact of course, Ober does not describe any comparison ever being made between a first set of reference signals (e.g. below threshold signals) and a second set of reference signals (e.g. above threshold signals). But even if one chooses to suppose that Ober teaches a set-up mode in which both above threshold and below threshold signals must for some reason inherently be present, nothing suggests that the device ever compares the two kinds of signals with one another. Rather, each kind of signal is compared with the threshold level.

Applicant further and respectfully notes that the Examiner states that Ober inherently teaches a distinguishing of the first signals from the second signals via a measurement of greatest in magnitude. That, we respectfully submit to be contradictory

and incorrect. The identification of a particular unique signal (that one which is greatest in magnitude) cannot be a distinguishing criterion for differentiating between two kinds of signal. If Ober's threshold were to be set at the level of the greatest magnitude signal, it would not be expected that there would ever be an event triggering the feedback signal.

Applicant therefore and respectfully submits that it is far from inherent that Ober teaches a set-up mode at all, particularly one in which first and second kinds of reference signals corresponding to two kinds of muscle activity are compared in the claimed device to identify therefrom a distinguishing criterion on the basis of which the signals can be differentiated from one another, as is required by Applicant's claims 52 and 68.

Applicant also respectfully points out that claim 56 requires registering and storing of the signals indicative of muscle activity over a time interval. This is used for the performance of the comparison of the first and second kinds of reference signal. This is not disclosed in Ober. The recorder 50 in Ober is not for this purpose, but only for recording the number of times that the stimulation signal is emitted.

Newly presented claim 69 builds on the above by requiring FFT analysis of the signals.

Claim Rejections Under 35 U.S.C. §103(a)

Claims 60, 61, 64, and 66 are rejected under 35 U.S.C. §103(a) as being unpatentable over Ober in view of various combinations United States Patent No. 6,636,763 to Junker (hereinafter "Junker"), United States Patent No. 4,993,423 to Stice (hereinafter "Stice"), and United States Patent No. 5,368,043 to Sunouchi (hereinafter "Sunouchi"). Applicant respectfully traverses the rejections.

Applicant respectfully notes that claims 60, 61, 64, and 66 depend from claim 52. As such, for at least the reasons discussed in the 102 remarks, Ober does not teach every

element of claims 60, 61, 64, and 66. Since none of Junker, Stice, or Sunouchi, taken alone or in combination remedy the deficiencies of Ober, any proposed combination of Ober, Junker, Stice, and Sunouchi does not teach every element of Applicant's claims 60, 61, 64, and 66. Thus, Applicant respectfully asserts that claims 60, 61, 64, and 66 are not obvious over any proposed combination of Ober, Junker, Stice, and Sunouchi. Further, as any proposed combination of Ober, Junker, Stice, and Sunouchi does not teach every element of Applicant's claims, combination or modification of the above references would not be obvious, or offer any reasonable chance of success.

Conclusion

All of the objections and rejections are herein overcome. In view of the foregoing, it is respectfully submitted that the instant application is in condition for allowance. No new matter is added by way of the present Amendments and Remarks, as support is found throughout the original filed specification, claims and drawings. Prompt issuance of Notice of Allowance is respectfully requested.

The Examiner is invited to contact Applicant's attorney at the below listed phone number regarding this response or otherwise concerning the present application.

Applicant hereby petitions for any necessary extension of time required under 37 C.F.R. 1.136(a) or 1.136(b) which may be required for entry and consideration of the present Reply.

If there are any charges due with respect to this Amendment or otherwise, please charge them to Deposit Account No. 06-1130 maintained by Applicant's attorneys.

Respectfully submitted,

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